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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,950	XUE ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 10, 2007 has been entered. Claims 2 and 20 were previously cancelled. Claims 1 and 3-19 are pending.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application, by application number and filing date, is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not correctly state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Specifically, the oath or declaration does not have the correct statement with respect to the duty to disclose. This applies to all applications, not just reissue applications. The Examiner suggests obtaining the most recent version of the PTO/SB/01 which states, "I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application".

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. ***Claims 1, 3 and 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (U.S. 4,136,690) (herein Anderson) in view of Kardys.*** As to Claims 1 and 3, Anderson discloses a method of analysis using an electrocardiogram (ECG) signal comprising measuring a 2-D QRS-T angle, defining a relationship, between the QRS peak vector, read as depolarization, and the T-wave peak vector, read as repolarization. Anderson discloses that the 2-D QRS-T angle is "successively stored" and the Examiner interprets this to mean that values of the 2-D QRS-T angle are determined for a first beat of the ECG, a second beat of the ECG and successive beats of the ECG (see Anderson column 2, lines 19-50 and column 3, lines 8-64). Anderson further discloses that each determined and stored 2-D QRS-T angle is tallied into one of a number of known angular ranges for analysis, evaluation and comparison between each 2-D QRS-T angle where the analysis, evaluation and comparison "calculates" a variation between the successfully stored values (see Anderson column 3, lines 57-67, column 7, lines 43-47 and column 8, lines 59-66).

Specifically, Anderson "calculates" differences/variations between each determined and stored 2-D QRS-T angle since each angle is evaluated via classifying circuit 52 and tallied into one

of a plurality of angular ranges, the angular values of which are different and known (see Anderson column 7, lines 3-47). The Examiner considers "to calculate a variation" synonymous with "to determine a difference or variation by reasoning", "to estimate a difference or variation", "to evaluate a difference or variation" and/or "to gauge a difference or variation". It is inherent, that evaluated data output to display 76 and/or printer 78 (see Anderson column 8, lines 22-66) includes a determined difference/variation between successive 2-D QRST angles since the successive 2-D QRST angles are tallied into known and different angular ranges before the step of outputting. Counters 70 of Anderson accumulate the respective numbers of 2-D QRST angles determined on successive signatures to have fallen into each of the known and different angular ranges and such data is output as a graphic analytical record of results (see Anderson column 7, lines 3-55 and column 8, lines 3-66). Anderson expressly discloses that a counter 70 is provided for each known and different angular range to accumulate over successive heartbeats the number of determined 2-D QRS-T angles that are tallied into each angular range and the cumulative counts are displayed via display 76 or printers 78. Any output that includes two or more 2-D QRS-T angles, classified/evaluated/tallied into two or more known and different angular ranges includes an output of an evaluated/reasoned/calculated difference/variation between those two or more 2-D QRS-T angles since circuit 52 evaluated/reasoned/calculated those two or more 2-D QRS-T into two or more different angular ranges having two different known angular range values (see Anderson Abstract and columns 7-14).

It is inherent, or at least obvious to one having ordinary skill in the art at the time the invention was made that, although not expressly disclosed by Anderson, the accumulated data stored, displayed an/or printed and used for analysis in the method of Anderson "assesses a patient's cardiac vulnerability to sudden cardiac death" because any arrhythmias/ectopic foci present are detected and

classified and arrhythmias/ectopic foci are known precursor to sudden cardiac death. The Examiner takes the position that a method, which classifies arrhythmias/ectopic foci present in a patient's ECG signal, inherently assesses "vulnerability" to "sudden cardiac death" since arrhythmia/foci present in a patient's ECG indicates that a patient is more "vulnerable" to experiencing "sudden cardiac death". Anderson discloses the claimed invention as discussed above except that it is not specified that the method calculate a 3-D QRS-T angle from a set of orthoganalized X, Y and Z leads of the ECG and then use the 3-D QRS-T angle to asses a patient's cardiac vulnerability to sudden cardiac death by calculating a variation between successively calculated 3-D QRS-T angles.

Kardys, however, teaches that the spatial QRS-T angle, read as the 3-D QRS-T angle since it is disclosed to be calculated from a set of orthoganalized X, Y and Z leads of the ECG, is a strong and independent predictor of cardiac mortality that is less susceptible to noise. Kardys also discloses that calculation of the 3-D QRS-T angle can be easily implemented on modern electrocardiographs, which are nowadays equipped with sufficient computing power. Kardys teaches that the abnormal 3-D QRS-T angles are associated with worse cardiac outcomes such as fatal cardiac events (see Kardys pages 1357-1364). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Anderson in view of Kardys to utilize a 3-D QRS-T angle calculated from a set of orthoganalized X, Y and Z leads of the ECG since such a modification would allow for assessment a patient's worsening condition and since such a modification may be easily implemented and is less susceptible to noise.

6. As to Claims 6 and 7, the previously modified Anderson reference discloses the claimed invention except the method does not specify selecting the first beat and the second beat from median beats or mean beats. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Anderson in view of Kardys to include

selecting the first beat and the second beat from median or mean beats since it was known in the art that such a statistical selection method is used to provide means for lessening the affect that spurious signals have on the diagnosis results.

7. ***Claims 4-5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kardys as applied to claim 1 above, and further in view of Burnes (U.S. 2004/0220635).*** As to Claims 4 and 5, the previously modified Anderson reference discloses the claimed invention as discussed above except that it is not specified that the method include defining the relationship between depolarization and repolarization to include a QRS duration and a T/QT duration.

Burnes, however, discloses a method using an ECG comprising determining an activation recovery interval (ARI), read as a relationship, as the difference between activation time, read as depolarization, and recovery time, read as repolarization (see Burnes page 8, Claim 6). Burnes also discloses that if a subsequent comparison of a prior dispersion of ARI reveals an increased dispersion of ARI, a worsening heart failure condition is declared (see Burnes page 5, paragraphs 48-51). It is inherent that the subsequent ARI is determined for a first beat and the prior dispersion of ARI determined for a second beat. It is inherent or at least obvious to one having ordinary skill in the art at the time the invention was made that, although not expressly disclosed by Burnes, the detection of increased dispersion disclosed is capable of assessing a patient's cardiac vulnerability to sudden cardiac death because the method indicates a worsening of heart failure and/or increased risk of arrhythmias, both precursors and/or indicators of sudden cardiac death. In addition the detection of increased dispersion disclosed by Burnes is inherently indicative of an increased "vulnerability" to "sudden cardiac death". Burnes further discloses that determination of the dispersion of the ARI includes QRS duration and QT duration and QRS duration and T duration (see Burnes page 1, paragraphs 3-5 and page 6, paragraphs 53-55). It would have been obvious to one having ordinary

skill in the art at the time the invention was made to modify the method of Anderson in view of Kardys and Burnes to include defining the relationship between depolarization and repolarization to further include QRS duration and T/QT duration in order to provide indication of a worsening of heart failure and/or increased risk of arrhythmias, both precursors and/or indicators of sudden cardiac death.

8. As to Claim 8, the previously modified Anderson reference discloses the claimed invention as discussed above except that it is not specified that the first beat be within a first range of heart rate and the second beat be within a second range of heart rate that is different from the first.

Burnes, however, discloses a method using an ECG comprising determining an activation recovery interval (ARI), read as a relationship, as the difference between activation time, read as depolarization, and recovery time, read as repolarization (see Burnes page 8, Claim 6). Burnes also discloses that if a subsequent comparison of a prior dispersion of ARI reveals an increased dispersion of ARI, a worsening heart failure condition is declared (see Burnes page 5, paragraphs 48-51). It is inherent that the subsequent ARI is determined for a first beat and the prior dispersion of ARI determined for a second beat. It is inherent or at least obvious to one having ordinary skill in the art at the time the invention was made that, although not expressly disclosed by Burnes, the detection of increased dispersion disclosed is capable of assessing a patient's cardiac vulnerability to sudden cardiac death because the method indicates a worsening of heart failure and/or increased risk of arrhythmias, both precursors and/or indicators of sudden cardiac death. In addition the detection of increased dispersion disclosed by Burnes is inherently indicative of an increased "vulnerability" to "sudden cardiac death". Burnes further discloses that dispersion measurements may be performed on a periodic basis for monitoring heart failure status, monitoring arrhythmia risk, or optimizing a therapy in order to reduce dispersion, for example by adjusting cardiac pacing parameters during

CRT or adjusting the dosage of a drug therapy (see Burnes page 5, paragraph 47). It is inherent the such an optimization would include selecting a first beat from an ECG signal obtained from the patient prior to the event and selecting the second beat from an ECG signal obtained from the patient after the event. It is also inherent that a first beat selected in this manner would be from an ECG having a heart rate within a first range and a second beat selected in this manner would be from an ECG having a heart rate within a second range that is different from the first due to the administered therapy. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Anderson in view of Kardys and Burnes to include a step of selecting the first beat from an ECG obtained from the patient prior to an event and selecting the second beat from an ECG obtained from the patient after the event where the event includes administering a pharmaceutical drug to a patient in order optimize the invention.

9. ***Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kardys as applied to claim 1 above, and further in view of Kaplan et al. (U.S. 4,732,157) (herein Kaplan).*** The previously modified Anderson reference discloses the claimed invention as discussed above except that the method does not further comprise conduction a time series analysis of the first and second values.

Kaplan, however, teaches that is known to use a time series to quantify beat-to-beat variability in an ECG waveform in order to determine susceptibility to ventricular fibrillation (see Kaplan column 5, lines 12-23 and column 6, lines 1-22). Kaplan also discloses that an objective of the time series analysis on a plurality of beats is to derive a numerical parameter from the ECG, which is associated with susceptibility to ventricular fibrillation (see Kaplan Abstract and column 2, lines 25-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Anderson in view of Kardys and Kaplan to include

a time series analysis in order to derive a numerical parameter associated with susceptibility to ventricular fibrillation.

10. ***Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kardys as applied to claim 1 above, and further in view of Verrier et al. (U.S. 5,265,617) (herein Verrier '617).*** The previously modified Anderson reference discloses the claimed invention as discussed above except that the method does not further comprise using a cardiac parameter or heart rate variability in addition to the ECG signal to asses the patient's cardiac vulnerability to sudden cardiac death.

Verrier '617, however, discloses a method and apparatus for the non-invasive diagnosing of cardiac vulnerability to ventricular fibrillation that comprises evaluating heart rate variability in addition to T-wave alternans of the ECG signal (see Verrier '617 Title and Abstract). Verrier '617 discloses that heart rate variability is a measure of autonomic influence, which is a major factor in triggering cardiac arrythmias and that by simultaneous analysis of the ECG signal and heart rate variability allows for the extent and cause of cardiac vulnerability to be assessed so that drug therapy may be tailored per patient (see Verrier '617 column 4, lines 54-67 and column 5, lines 1-5). The Examiner takes the position that heart rate variability is synonymous with a cardiac parameter. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Anderson in view of Kardys and Verrier '617 to include simultaneous evaluation of heart rate variability in addition to the ECG signal to better asses the patient's vulnerability to sudden cardiac death and to tailor a drug therapy as best to treat the patient.

11. ***Claims 12 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kardys as applied to claim 1 above, and further in view of Ralph et al "Blunted arterial baroreflec causes 'pathological' heart rate turbulence", cited by Applicant***

(herein Ralph). The previously modified Anderson discloses the claimed invention as discussed above except that the method does not further comprise using heart rate turbulence in addition to the ECG signal.

Ralph, however, teaches that it is known to utilize a characteristic of baroreflex function such as heart rate turbulence (either onset or slope) as set forth in the Abstract and the third paragraph on page 2, as a superior predictor of sudden cardiac death. In particular, Ralph discloses that turbulence onset is defined prior to a premature ventricular contraction and after the premature ventricular contraction and turbulence slope is defined within the first 20 sinus-rhythm intervals after the premature contraction. The Examiner takes the position that PVCs naturally have varying cycle lengths and varying morphologies. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Anderson in view of Kardys, to include heart rate turbulence in addition to analysis of the ECG signal as taught by Ralph, since such a modification would provide a substantial improvement in the ability to predict sudden cardiac death.

12. ***Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kardys and Ralph as applied to claims 1 and 12 above, and further in view of Verrier et al. (U.S. 5,560,370) (herein Verrier '370).*** The previously modified Anderson reference discloses the claimed invention as discussed above except that the method does not comprise using data corresponding to blood pressure change in addition to heart rate turbulence to asses the patient's cardiac vulnerability to sudden cardiac death.

Verrier '370, however, discloses a method for prediction of cardiac electrical instability that uses baroreflex sensitivity as an additional indicator of cardiac electrical instability and that this sensitivity may be non-invasively characterized as blood pressure (see Verrier '370 column 20, lines

34-45). It would have been obvious to one having ordinary skill in the art to modify the method of Anderson in view of Kardys, Ralph and Verrier to include using data corresponding to blood pressure in addition to heart rate turbulence to non-invasively asses the patient's cardiac vulnerability to sudden cardiac death.

13. ***Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kardys and Ralph as applied to claims 1 and 12 above, and further in view of Burnes.*** The previously modified Anderson reference discloses the claimed invention except that selecting the first beat from an electrocardiogram signal obtained from the patient is not disclosed to occur prior to an event and selecting the second beat from an electrocardiogram signal obtained from the patient is not disclosed to occur at least one of during and after the event where the event includes at least one of administering a pharmaceutical drug to a patient, pacing the patient using exercise, and pacing the patient using an implanted pacemaker.

Burnes, however, discloses a method using an ECG comprising determining an activation recovery interval (ARI), read as a relationship, as the difference between activation time, read as depolarization, and recovery time, read as repolarization (see Burnes page 8, Claim 6). Burnes also discloses that if a subsequent comparison of a prior dispersion of ARI reveals an increased dispersion of ARI, a worsening heart failure condition is declared (see Burnes page 5, paragraphs 48-51). It is inherent that the subsequent ARI is determined for a first beat and the prior dispersion of ARI determined for a second beat. In addition the detection of increased dispersion disclosed by Burnes is capable of assessing a patient's cardiac vulnerability to sudden cardiac death because the method indicates a worsening of heart failure and/or increased risk of arrhythmias, both precursors and/or indicators of sudden cardiac death. Bunres also discloses that dispersion measurements may be performed on a periodic basis for monitoring heart failure status, monitoring arrhythmia risk, or

optimizing a therapy in order to reduce dispersion, for example by adjusting cardiac pacing parameters during CRT or adjusting the dosage of a drug therapy (see Burnes page 5, paragraph 47). It is inherent the such an optimization would include selecting a first beat from an ECG signal obtained from the patient prior to the event and selecting the second beat from an ECG signal obtained from the patient after the event. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Anderson in view of Kardys, Ralph and Burnes to include a step of selecting the first beat from an ECG obtained from the patient prior to an event and selecting the second beat from an ECG obtained from the patient after the event where the event includes administering a pharmaceutical drug to a patient in order optimize the invention.

14. ***Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kardys and Kaplan.*** The previously modified Anderson reference discloses the claimed invention as discussed above except that the method does not further comprise conducting a time series analysis of the first and second values.

Kaplan, however, teaches that is known to use a time series to quantify beat-to-beat variability in an ECG waveform in order to determine susceptibility to ventricular fibrillation (see Kaplan column 5, lines 12-23 and column 6, lines 1-22). Kaplan also discloses that an objective of the time series analysis on a plurality of beats is to derive a numerical parameter from the ECG, which is associated with susceptibility to ventricular fibrillation (see Kaplan Abstract and column 2, lines 25-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Anderson in view of Kardys and Kaplan to include a time series analysis in order to derive a numerical parameter associated with susceptibility to ventricular fibrillation.

15. ***Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson in view of Kardys and Kaplan as applied to claim 18 above, and further in view of Verrier '617.*** The previously modified Anderson reference discloses the claimed invention as discussed above except that the method does not further comprise using a cardiac parameter or heart rate variability in addition to the ECG signal to asses the patient's cardiac vulnerability to sudden cardiac death.

Verrier '617, however, discloses a method and apparatus for the non-invasive diagnosing of cardiac vulnerability to ventricular fibrillation that comprises evaluating heart rate variability in addition to T-wave alternans of the ECG signal (see Verrier '617 Title and Abstract). Verrier '617 discloses that heart rate variability is a measure of autonomic influence, which is a major factor in triggering cardiac arrythmias and that by simultaneous analysis of the ECG signal and heart rate variability allows for the extent and cause of cardiac vulnerability to be assessed so that drug therapy may be tailored per patient (see Verrier '617 column 4, lines 54-67 and column 5, lines 1-5). The Examiner takes the position that heart rate variability is synonymous with a cardiac parameter. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Anderson in view of Kardys, Kaplan and Verrier '617 to include simultaneous evaluation of heart rate variability in addition to the ECG signal to better asses the patient's vulnerability to sudden cardiac death and to tailor a drug therapy as best to treat the patient.

Response to Arguments

16. Applicant's arguments filed August 10, 2007 have been fully considered but they are not persuasive. In response to Applicant's argument that Anderson does not teach or fairly suggest the steps of "calculating" a variation between the first value representative of the 2D-QRST angle and the second value representative of the 2D-QRST angle and outputting the calculated variation to an output device for analysis identical to the "calculating" steps discussed by Applicant at page 5,

paragraph 23 through page 7, paragraph 28 of Applicant's disclosure (see pages 7-8 of the Remarks), Applicant misinterprets the principle that claims are interpreted in light of the specification. Although these methods or steps of "calculating" are found as examples or embodiments in the specification, they were not claimed explicitly. Nor were the words that are used in the claims defined in the specification to require these limitations. A reading of the specification provides no evidence that these limitations (i.e. the steps of "calculating" discussed by Applicant at page 5, paragraph 23 through page 7, paragraph 28 of Applicant's disclosure) must be imported into the claims to give meaning to disputed terms. *Constant v. Advanced Micro-Devices In.*, 7 USPQ2d 1064.

The Office determines the scope of claims in patent applications, not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification" as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). During examination, the claims must be interpreted as broadly as their terms reasonably allow and the words of claims are given their "plain meaning" unless such meaning is inconsistent with the specification. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004), *In re Zletz,* 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) and *Chef America, Inc. v. Lamb-Weston, Inc.,* 358 F.3d 1371, 1372, 69USPQ2d 1857 (Fed. Cir. 2004). As previously discussed, Anderson "calculates" differences/variations between each determined and stored 2-D QRS-T angle since each angle is evaluated via classifying circuit 52 and tallied into one of a plurality of angular ranges, the angular values of which are different and known (see Anderson column 7, lines 3-47) and since the Examiner considers "to calculate a variation" synonymous with "to determine a difference or variation by reasoning", "to estimate a difference or variation", "to evaluate

a difference or variation" and/or "to gauge a difference or variation". "Calculating a variation" was not defined in Applicant's specification in such a way that precludes such interpretation(s) of "to calculate a variation" or "calculating a variation".

17. In response to Applicant's argument that there is no suggestion to combine the references of Anderson and Kardys (see the last two lines of page 8 and the first three lines of page 9 of Applicant's Remarks), the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As previously discussed, both above in this Office Action and in the Final Rejection of May 21, 2007, Kardys expressly teaches that the special QRS-T angle, read as the 3-D QRS-T angle is a strong and independent predictor of cardiac mortality that is stronger than any of the classical cardiovascular risk factors and ECG risk indicators and further that it provides additional value compared to such classical risk factors in predicting fatal cardiac events (see Kardys Abstract page 1357). Kardys also discloses that calculation of the 3-D QRS-T angle can be easily implemented on modern electrocardiographs, which are nowadays equipped with sufficient computing power. Kardys teaches that the abnormal 3-D QRS-T angles are associated with worse cardiac outcomes such as fatal cardiac events (see Kardys pages 1357-1364). As previously discussed by the Examiner, it is these benefits, which are expressly taught by the Kardys reference, that provide the motivation to modify the prior art of Anderson. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Anderson to utilize a 3-D QRS-T angle calculated from a set of orthoganalized X, Y and Z leads instead of the 2-D QRS-T

angle since such a modification would allow for reliable and strong assessment a patient's worsening condition and since such a modification may be easily implemented and is less susceptible to noise as expressly taught by Kardys.

18. In response to Applicant's arguments based upon the age of the references (see pages 8-9 of the Remarks), contentions that the reference patents are old is not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. *In re Neal*, 179 USPQ 56 (CCPA 1973) and *In re Wright*, 569 F.2d 1124, 1127, 193 USPQ 332, 335 (CCPA 1977) (100 year old patent was properly relied upon in a rejection based on a combination of references.). See also *Ex parte Meyer*, 6 USPQ2d 1966 (Bd. Pat. App. & Inter. 1988) (length of time between the issuance of prior art patents relied upon (1920 and 1976) was not persuasive of unobviousness).

19. In response to Applicant's arguments against the Anderson, Kardys and Kaplan references individually (see page 11 of the Remarks), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

21. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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